UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

In re INTUNIV ANTITRUST LITIGATION

C.A. No. 16-cv-12653-ADB (Direct) 16-cv-12396-ADB (Indirect)

PUBLIC VERSION

This Document Relates to: All Actions

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS'
MOTION TO EXCLUDE THE OPINION AND TESTIMONY OF
PLAINTIFFS' EXPERTS MARTHA A. STARR AND CHRISTOPHER F. BAUM

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INTRODUCTION

Defendants Actavis Elizabeth LLC, Actavis LLC, and Actavis Holdco U.S., Inc.

(collectively "Actavis") and Shire LLC and Shire US Inc. (collectively, "Shire" and together with Actavis, "Defendants"), move to exclude the opinion and testimony of Plaintiffs' experts Martha A. Starr, Ph.D. and Christopher F. Baum, Ph.D. To succeed on their claims under Sections 1 and 2 of the Sherman Act, Plaintiffs must prove that Shire possessed "market power" (for a Section 1 claim) or "monopoly power" (for a Section 2 claim) in the relevant market. To that end, Dr. Starr and Dr. Baum offer opinions

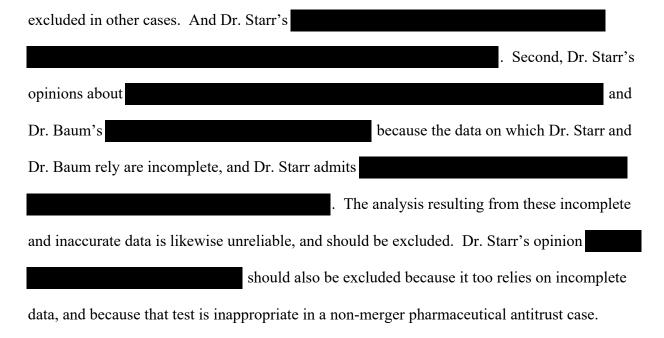
Dr. Starr further opines to

Dr. Starr's testimony should be excluded for two primary reasons. First, she offers opinions that are not reliable, and therefore not helpful to the finder of fact. Dr. Starr's opinions about are unreliable because they are based on incomplete data and demonstrate at most correlation, not causation. Dr. Starr's opinion that because it leads to the absurd result that nearly every pharmaceutical company (including every producer of generic pharmaceuticals) is a monopolist—which is why this sort of "evidence" has been

¹ See, e.g., In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., 2018 WL 563144, at *4 & n.5 (D. Mass. Jan. 25, 2018). Defendants refer to "market power" throughout this memorandum because failure to demonstrate market power is a fortiori failure to demonstrate monopoly power. *Id.* ("[A] showing of monopoly power for the purposes of Section 2 is held to a higher standard than for Section 1.") (citation omitted) (collecting cases).

² See, e.g., Apr. 1, 2019 Expert Report of Martha A. Starr ¶ 9 (Starr Report"), attached as Ex. 40A; Apr. 1, 2019 Expert Report of Christopher F. Baum p. 2 ("Baum Report"), attached as Exhibit 168A. All citations to exhibits refer to exhibits attached to the Declaration of Joshua S. Barlow, Esq. In Support Of Defendants' Motion for Summary Judgment And Related Filings (the "Barlow Decl.").

 $^{^{3}}$ *E.g.*, Ex. 40A (Starr Report) ¶¶ 7-8.



Dr. Baum's analysis relies on these same data, and his opinions therefore suffer from the same infirmities, and should be excluded for the same reasons.

LEGAL STANDARD

Pursuant to Federal Rule of Evidence 702, "[a] qualified expert may testify in the form of an opinion or otherwise if: (a) the expert's . . . knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based upon sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case." Rule 702 "requires district courts to 'ensur[e] that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand' before admitting it into evidence."

The latter *Daubert* requirement, ensuring that the expert's testimony is relevant to the task at hand, "seeks to ensure that there is an adequate fit between the expert's methods and [her]

⁴ Samaan v. St. Joseph Hosp., 670 F.3d 21, 31 (1st Cir. 2012) (quoting Fed. R. Evid. 702).

⁵ In re Nexium (Esomeprazole) Antitrust Litig., 842 F.3d 34, 52 (1st Cir. 2016) (alteration in original) (quoting Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 597 (1993)).

conclusions," and "addresses the problem that arises when an expert's methods . . . yield results that bear a dubious relationship to the questions on which [s]he proposes to opine." A court's *Daubert* analysis is therefore "not limited to an appraisal of an expert's credentials and techniques but also entails an examination of [her] conclusions to determine whether they flow rationally from the methodology employed." If this analysis "reveals 'that there is simply too great an analytical gap between the data and the opinion proffered,' the expert's testimony should be excluded."

This inquiry is not to be undertaken lightly: "Ever since the Supreme Court decision in Daubert..., district court judges have understood that they play a vital 'gatekeeper' role in ensuring the integrity of expert testimony." "The Court must be vigilant in exercising its gatekeeper role because of the latitude given to expert witnesses to express their opinions on matters about which they have no firsthand knowledge and because an expert's testimony may be given substantial weight by the jury due to the expert's status." ¹⁰

"The ultimate purpose of the *Daubert* inquiry is to determine whether the testimony of the expert would be helpful to the jury in resolving a fact in issue." Expert testimony to the jury about "purely legal issues" such as "the law to be applied to the resolution of the dispute before them" is "rarely admissible" since "the jury does not decide such pure questions of law" and expert testimony on these issues "is not helpful to the jury." Therefore, in accordance with

⁶ Samaan, 670 F.3d at 32.

^{&#}x27; Id.

⁸ *Id.* (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)); *see also Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co.*, 161 F.3d 77, 81 (1st Cir. 1998) ("[T]rial judges may evaluate the data offered to support an expert's bottom-line opinions to determine if that data provides adequate support").

⁹ Ambit Corp. v. Delta Airlines, Inc., 707 F. Supp. 2d 74, 76 (D. Mass. 2010).

¹⁰ WBIP, LLC v. Kohler Co., 965 F. Supp. 2d 170, 173 (D. Mass. 2013).

¹¹ Cipollone v. Yale Indus. Prods., Inc., 202 F.3d 376, 380 (1st Cir. 2000).

¹² Nieves-Villanueva v. Soto-Rivera, 133 F.3d 92, 99-100 (1st Cir. 1997).

their important gatekeeping role, "[c]ourts generally have held legal opinion testimony inadmissible under Fed. R. Evid. 702."13

BACKGROUND

Dr. Starr opines that,	
	Dr. Starr further
opines that	
	Dr. Starr used
	, and she relied on
Meanwhile, Dr. Baum purports to	
Meanwhite, Dr. Baum purports to	
	From this analysis, Dr. Baum

¹³ Gomez v. Rivera Rodriguez, 344 F.3d 103, 114 (1st Cir. 2003).
14 Ex. 40A (Starr Report) ¶ 7; see also id. ¶¶ 55-72.
15 Id. ¶ 8; see also id. ¶¶ 82-103.
16 See, e.g., id. ¶¶ 80, 92-96.
17 Ex. 168A (Baum Report) ¶¶ 7-10.

concludes that **ARGUMENT** I. DR. STARR'S OPINION Dr. Starr's Opinions A. Are Unreliable. Dr. Starr opines As an initial matter, and as discussed in detail in II.B, infra, Dr. Starr's analysis of price is In fact, Dr. Starr herself admits This opinion is not reliable because and the Court should exclude it for that reason alone. For example, as the Court noted in denying certification of an IPP class, there were likely "thousands" of consumers for whom the price paid for generic Intuniv was no lower than the price paid for brand Intuniv prior to generic entry, due to coupons.²² In other words, for those consumers there was no price decline. Dr. Starr's analysis

¹⁸ *Id.* p. 2. ¹⁹ Dr. Starr testified that

[.] Ex. 41 (Starr Tr.) 188.

²⁰ Ex. 40A (Starr Report) ¶ 64; see also id. ¶¶ 7, 65-66.

²² Mem. & Order at 8 & n.5, In re Intuniv Antitrust Litig., No. 16-cv-12396 (D. Mass. Aug. 21, 2019), ECF No. 230.

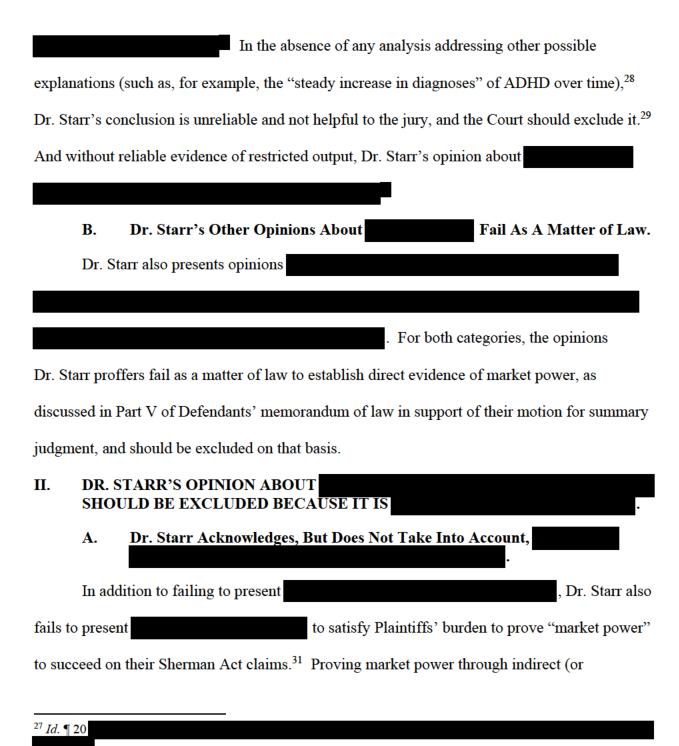
. This one example highlights the
unreliability of Dr. Starr's analysis.
Moreover, Dr. Starr's opinion on this point should be excluded because
Dr. Starr separately opines
that,
Assuming that Dr. Starr intended for this opinion to be considered together
with her , Dr. Starr's analysis is not
reliable because her is wholly speculative. Dr. Starr's entire
conclusory analysis can be summarized in one sentence from her report:
But this opinion simply
. Dr. Starr, experienced
economist though she may be,
. And Dr. Starr offers

²³ See Coastal Fuels of P.R., Inc. v. Caribbean Petroleum Corp., 79 F.3d 182, 196 (1st Cir. 1996) ("A plaintiff can . . . show direct evidence of market power []perhaps by showing actual supracompetitive prices and restricted output") (emphasis added). Defendants have moved for partial summary judgment on the issue of market power, in a motion submitted contemporaneously herewith. Defendants refer to the memorandum of law accompanying that motion ("Defs.' MSJ Mem.") and incorporate by reference the arguments made therein. See Defs.' MSJ Mem. at Part V.

²⁴ Ex. 40A (Starr Report) ¶¶ 7, 70-72.

 $^{^{25}}$ *Id.* ¶ 72.

²⁶ *Id.* ¶ 72 & Figure 5.



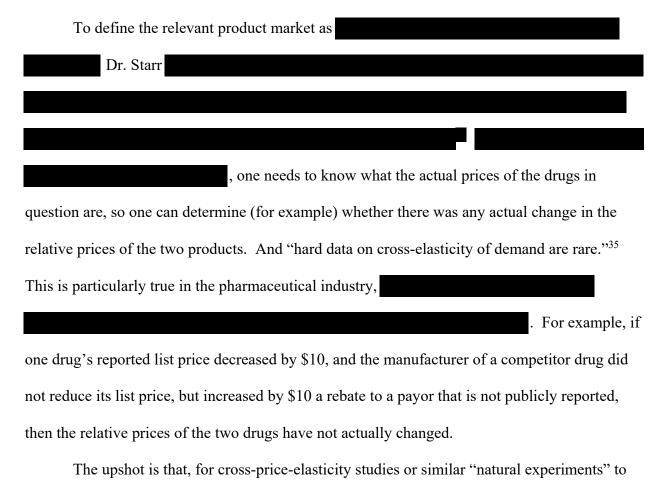
²⁸ Rachel Bluth, *ADHD Numbers Are Rising, and Scientists Are Trying to Understand Why*, Wash. Post, Sept. 10, 2018, https://wapo.st/2JLT8Ey.

²⁹ See, e.g., Joiner, 522 U.S. at 146 ("[N]othing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert."); Samaan, 670 F.3d at 33-34 (excluding expert opinion because, among other things, "[c]orrelation is not causation" and fit between expert's methods and data was therefore inadequate).

³⁰ See Solodyn, 2018 WL 563144, at *12.

³¹ See id. at *4 & n.5.

"circumstantial") evidence requires properly defining the relevant product market³² by "examining both the substitutes that a consumer might employ and 'the extent to which consumers will change their consumption of one product in response to a price change in another, i.e., the cross-elasticity of demand." ³³



below, Dr. Starr

work, knowledge of the actual prices paid by price-sensitive actors is crucial. But, as discussed

In these

³² *Id.* at *5.

³³ Flovac, Inc. v. Airvac, Inc., 817 F.3d 849, 854 (1st Cir. 2016) (quoting Eastman Kodak Co. v. Image Tech. Servs., Inc., 504 U.S. 451, 469 (1992)).

³⁴ See, e.g., Ex. 40A (Starr Report) ¶¶ 54, 73.

³⁵ Alaska Elec. Pension Fund v. Bank of Am. Corp., 306 F. Supp. 3d 610, 619 (S.D.N.Y. 2018).

circumstances, Dr. Starr's	is simply unreliable because her		
analyses are based on flawed, incomplete data.			
Dr. Starr acknowledges that			
	Dr. Starr admits		
	Thus, according to Dr. Starr,		
Dr. Starr further acknowledges that			

 ³⁶ Ex. 40A (Starr Report) ¶ 24.
 ³⁷ Id. ¶ 25.
 ³⁸ Id.; Ex. 41 (Starr Tr.) 28 ().

39 Ex. 40A (Starr Report) ¶ 32.

40 Id. ¶¶ 26, 32.

41 Ex. 41 (Starr Tr.) 39.

All of these rebates, discounts, coupons, etc. are significant in the pharmaceutical

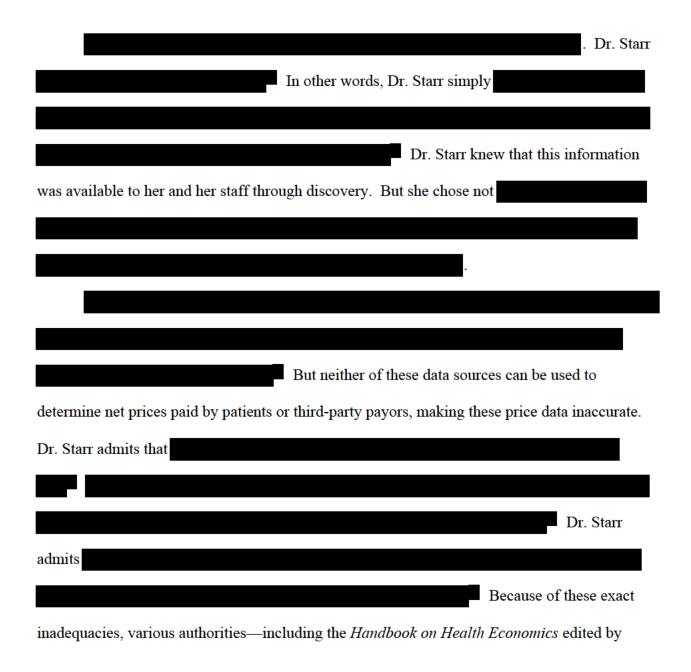
industry because they affect the actual prices paid by the patient and the third-party payor. As Dr. Starr admitted, To examine price sensitivity, one would need to look at the actual net price paid by the actors who are price sensitive, since any other measure of price would be inaccurate, and would not accurately reflect the facts. , and her analysis is therefore rendered unreliable by incomplete data. В. Dr. Starr Rendering Her Analysis Inaccurate. Dr. Starr Dr. Starr admits that she Dr. Starr also admits Dr. Starr, therefore, admits . Nor did Dr. Starr

⁴² Ex. 40A (Starr Report) ¶ 43 (emphasis added).

⁴³ Ex. 41 (Starr Tr.) 37.

⁴⁴ Id. 39.

⁴⁵ *Id.* 48-49.



⁴⁶ E.g., id. 52

⁴⁷ *Id*. 116-17.

⁴⁸ See id. 74-75.

⁴⁹ *Id.* 82-83.

⁵⁰ Ex. 40A (Starr Report) ¶ 38; see also Ex. 41 (Starr Tr.) 85 (same).

⁵¹ Ex. 41 (Starr Tr.) 88-89.

Plaintiffs' expert Dr. McGuire—warn that the data sets Dr. Starr used "have significant measurement error in the price variable" that make them unfit for analyzing elasticities.⁵²



⁵² Fiona Scott Morton & Margaret Kyle, *Markets for Pharmaceutical Products*, in 2 Handbook of Health Economics 763, 790 (2012).

⁵³ Ex. 41 (Starr Tr.) 194. 54 See Ex. 40A (Starr Report) ¶¶ 83-89 & Figure 4.

⁵⁵ *Id*. ¶ 66.

⁵⁶ Ex. 41 (Starr Tr.) 189.

⁵⁷ See Ex. 40A (Starr Report) ¶¶ 90-91.

But of course it is relevant; indeed, it is a crucial input without which the analysis simply cannot work. The actual prices paid by patients and third-party payors—the net prices—are relevant because an expert's testimony must be "based on sufficient facts or data." 60

⁵⁸ Ex. 41 (Starr Tr.) 196-197. ⁵⁹ *Id.* 197-198.

⁶⁰ Fed. R. Evid. 702(b).

⁶¹ See Ex. 40A (Starr Report) ¶ 89. 62 Ex. 41 (Starr Tr.) 52.

⁶³ *Id.* 196-97.

Knowing the actual (net) prices that patients and third-party payors paid for Kapvay is crucial to understanding the effect of changes in guanfacine ER price on demand for Kapvay.

Dr. Starr herself admits that Her conclusion that Such opinion evidence, based only on Dr. Starr's "ipse dixit," should be excluded.⁶⁸

Dr. Starr's attempt to explain away these deficiencies is inadequate. She states only But here,

Plaintiffs were engaged in discovery for many months, and could have sought exactly these data through the discovery process. While it was Plaintiffs' right to elect, for whatever reason, not to obtain that information, their choice not to do so does not somehow make their inadequate data

⁶⁴ See id. 62.

 ⁶⁵ *Id*. 72.
 66 Ex. 40A (Starr Report) ¶ 32.

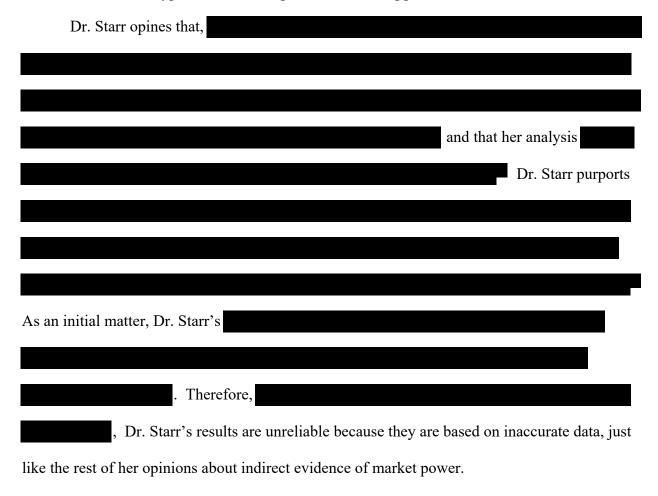
⁶⁷ Ex. 41 (Starr Tr.) 39.

⁶⁸ Joiner, 522 U.S. at 146.

⁶⁹ Ex. 40A (Starr Report) ¶ 44 (emphasis added).

reliable. The Court "may evaluate the data offered to support [Dr. Starr's] bottom-line opinions to determine if that data provides adequate support." Here, Dr. Starr's natural-experiment opinions are based on data that do not accurately reflect the actual prices paid by patients and third-party payors, and the Court should exclude them.

C. The Hypothetical Monopolist Test Is Inapplicable In This Context.



Moreover, as recently explained by Judge Bartle in FTC v. AbbVie, Inc., 73 the Hypothetical Monopolist Test is not an appropriate tool to use when attempting to determine the

⁷⁰ *Ruiz-Troche*, 161 F.3d at 81.

⁷¹ Ex. 40A (Starr Report) ¶¶ 8, 97, 103; see also id. ¶¶ 98-102.

⁷² *Id*. ¶ 99.

⁷³ 329 F. Supp. 3d 98 (E.D. Pa. 2018).

relevant product market in a non-merger pharmaceutical antitrust case. In other words, "[t]here is no indication that the . . . test is required or even applicable in a monopolization case such as this." Judge Bartle concluded, (see II.A, supra), that "the pharmaceutical market functions in a unique way," because of the dynamics of who selects a given drug and who actually pays for it. Further distinguishing the pharmaceutical industry, Judge Bartle noted that the result of the applicable regulatory framework is that "AB-rated generics are often priced at a substantial discount" compared to the brand drug, which has "vastly different costs associated with launch[]." Dr. Starr

Given that generic drugs are, by design, much less expensive to develop and launch than brand drugs, and so will be priced lower than the brand, the Hypothetical Monopolist Test is not a helpful tool in this context because "application of the [test] would result in a market limited to a brand-name drug and its AB-rated generic in almost every instance." Judge Bartle therefore "reject[ed]" plaintiffs' attempt to use the Hypothetical Monopolist Test as indirect evidence of market power in the relevant product market.

⁷⁴ *Id.* at 129.

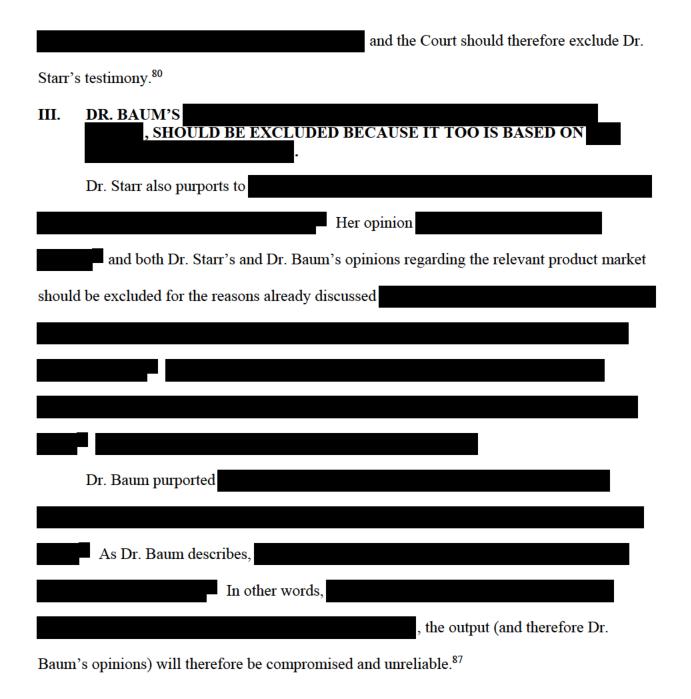
⁷⁵ Id. (quoting Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd. Co., 838 F.3d 421, 428 (3d Cir. 2016)).

⁷⁶ *Id.* at 130.

⁷⁷ Ex. 41 (Starr Tr.) 161-162.

⁷⁸ *AbbVie*, 329 F. Supp. 3d at 130.

⁷⁹ *Id*.



⁸⁰ Samaan, 670 F.3d at 32.

⁸¹ See Ex. 40A (Starr Report) ¶¶ 92-96.

⁸² See id.; Ex. 41 (Starr Tr.) 201.

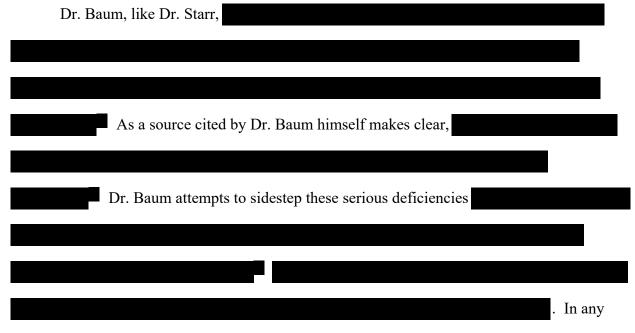
⁸³ Ex. 168A (Baum Report) ¶ 10; Ex. 41 (Starr Tr.) 203.

⁸⁴ Ex. 41 (Starr Tr.) 203.

⁸⁵ Ex. 168A (Baum Report) ¶ 9 (internal footnote omitted).

⁸⁶ Id. ¶ 9 n.19

⁸⁷ See SMS Sys. Maint. Servs., Inc. v. Dig. Equip. Corp., 188 F.3d 11, 25 (1st Cir. 1999) ("Expert opinions . . . are no better than the data and methodology that undergird them").



event, Dr. Baum is not an analyst working for a pharmaceutical company; he (like Dr. Starr) is an expert retained by Plaintiffs, who are engaged in litigation and therefore *could have* obtained this information through the discovery process. It is no answer to assert that in a non-litigation context the necessary data are not available. In this case, the data were available. Plaintiffs and their experts simply chose not to obtain them.

CONCLUSION

Dr. Starr's and Dr. Baum's opinions are undermined by serious deficiencies in the data upon which they chose to rely. This Court, "as gatekeeper, must 'ensure that there is an adequate fit between the expert[s'] methods and [their] conclusions." Here, there is a disconnect between Dr. Starr's and Dr. Baum's inputs, methodologies, and conclusions. The Court should exclude the opinions of Dr. Starr and Dr. Baum.

⁸⁸ June 24, 2019 Rebuttal Expert Report of Christopher F. Baum ¶ 11 ("Baum Rebuttal"), attached as Ex.168B.

⁸⁹ *Id*. ¶ 13.

⁹⁰ *Id.* ¶¶ 12-13.

⁹¹ Nexium, 842 F.3d at 52 (quoting Samaan, 670 F.3d at 32).

Dated: September 6, 2019

Respectfully submitted,

/s/ Joshua S. Barlow

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CERTIFICATE OF SERVICE

I, Christopher T. Holding, hereby certify that on September 6, 2019, I caused a copy of the foregoing document to be served on all counsel of record for Plaintiffs via email.

/s/ Christopher T. Holding